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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,208	01/26/2001	Juan F. Medrano	407T-923710US	7351

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EXAMINER	
SHUKLA, RAM R	

ART UNIT	PAPER NUMBER
1632	7

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/771,208	Applicant(s) MEDRANO ET AL.	
	Examiner Ram Shukla	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-76* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

DETAILED ACTION

1. Claims 1-76 are pending.

2. **Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Specifically the application fails to comply with CFR 1.821(d), which states:

(d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing " in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

For example, the specification discloses nucleotide sequence on page 24, line 30. However, this sequence is not identified by a sequence identifier and it is not clear whether the sequence has been listed in the sequence listing. Applicants are advised to carefully check the entire specification and list any other unlisted sequence in sequence listing.

For compliance with sequence rules, it is necessary to include the sequence in the "Sequence Listing" and identify them with SEQ ID NO. In general, any sequence that is disclosed and/or claimed as a sequence, i.e., as a string of particular bases or amino acids, and that otherwise meets the criteria of 37 CFR 1.821(a), must be set forth in the "Sequence Listing." (see MPEP 2422.03).

For the response to this office action to be complete, Applicants are required to comply with the Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7 and 62-63, drawn to a nucleic acid that encodes a gene product which when knocked out produces a high growth phenotype, classified in class 536, subclass 23.1.

II. Claims 8-22 and 27-36, drawn to a method of producing a knockout animal wherein the expression of Socs-2 gene is inhibited and the animal so produced, classified in class 800, subclass 8.

III. Claims 8 and 23-26, drawn to a knockout animal in which the expression of another gene, in addition to Socs-2 gene expression, has been inhibited, classified in class 800, subclass 8.

IV. Claim 37-46, 48, 59 and 60, drawn to a method of screening of an agent that alters a high growth phenotype using an in-vitro cell culture system, classified in class 435, subclass 375.

V. Claims 37, 47, 48, and 61, drawn to a method of screening of an agent that alters a high growth phenotype using an animal, classified in class 800, subclass 3.

VI. Claims 48-55 and 58, drawn to a method of screening of an agent that interacts with a Socs-2 nucleic acid in-vitro and alters expression of a high growth phenotype, classified in class 435, subclass 6.

VII. Claims 48-53 and 56-58, drawn to a method of screening of an agent that interacts with a Socs-2 protein in-vitro and alters expression of a high growth phenotype, classified in class 435, subclass 7.1.

VIII. Claim 64, drawn to a polypeptide that is encoded by a certain polynucleotide, classified in class 530, subclass 350.

IX. Claim 65, drawn to an antibody that specifically binds to a certain polypeptide, classified in class 530, subclass 387.1.

X. Claims 66-71, drawn to a nucleic acid for disrupting a Socs-2 gene, classified in class 435, subclass 320.1.

XI. Claims 72-76, drawn to an animal cell in which the endogenous Socs-2 has been disrupted, classified in class 435, subclass 325.

4. The inventions of Groups II and III encompass the limitations of the claim 8. Should any of these groups be elected for prosecution, the invention of claim 8 would be examined to the extent it encompasses the claimed invention.

5. The inventions of Groups IV, V, VI, and VII encompass the limitations of the claim 48. Should any of these groups be elected for prosecution, the invention of claim 48 would be examined to the extent it encompasses the claimed invention.

6. The inventions of Groups IV and V encompass the limitations of the claim 37. Should any of these groups be elected for prosecution, the invention of claim 37 would be examined to the extent it encompasses the claimed invention.

7. The inventions of Groups VI and VII encompass the limitations of the claim 58. Should any of these groups be elected for prosecution, the invention of claim 58 would be examined to the extent it encompasses the claimed invention.

8. Inventions of the groups I and VIII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to nucleic acids, polypeptide, antibody and an animal cell that have different structure, have different modes of operation and have different utilities. For example, the physical and chemical characteristics of a nucleic acid are different from those of a protein or an antibody. Likewise, the utility of a nucleic acid is different from those of a protein or an antibody, for example, a nucleic acid is used for making probes that can be used for northern or southern hybridization, whereas protein can be used for enzyme activity studies while an antibody can be used for western blotting or in-situ hybridization. Additionally, the characteristics of an antibody can vary depending upon the epitope or motif used for raising the antibody.

9. Inventions of groups I and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to nucleic acids that have different sequence structure, function and utility. The nucleic acid of group I is used for expressing wild type Socs-2 protein whereas the nucleic acid of group X is used for targeted disruption of an endogenous Socs-2 gene.

10. Inventions of the groups II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the invention of group II is drawn to Socs-2 gene knockout animal whereas the knockout animal has an additional gene knocked out. Therefore, the genotype as well as the phenotype and the utilities of the two animals would be different.

11. Inventions of the groups IV to VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods that use different components and steps and the steps of one method could not be used to practice another method. For example, the steps of screening for an agent that alters gene expression in vitro would be different from a method of in vivo screening since the in vitro method would not require administration of an agent to an animal. Likewise, the method of screening of compounds that interact with a protein would be different from that of screening method using a nucleic acid due to the difference in structures of nucleic acid and protein. Furthermore, an agent isolated by one method may not be isolated by another method.

12. Inventions of the groups I, IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of group I are used in practicing the methods of group IV and VI, however, the nucleic acid of group I can be used for practicing multiple methods such as that of groups IV and VI.

13. Inventions of the groups X, II, III and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of group X can be used for practicing materially different processing, such as for making the animal cell, knockout animal or double knockout animal of groups XI, II and III.

14. The methods of groups IV-VII are patentably distinct from the compositions of the groups I-III and VIII-XI because the methods of groups IV-VII can not be used to make the compositions of the groups I-III and VIII-XI.

15. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

When amending claims, applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c). For instructions, Applicants are referred to http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm.

Applicants are also requested to submit a copy of all the pending/under consideration claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (703) 305-3388.

Ram R. Shukla, Ph.D.

RAM R. SHUKLA, PH.D
PATENT EXAMINER